JUL 1 2 2000

K001401

AMT Manufacturing Inc.

510 Rowntree Dairy Rd. #5 ♦ Woodbridge, ON L4L 8H2 ♦ Canada ♦
ph:(416) 745-4739 ♦ fax:(905) 851-9767

SUMMARY OF SAFETY & EFFECTIVENESS – PREPARED May 2, 2000

- The AMT Therapeutic Table is identical to the VAX-D Therapeutic Table marketed under K951622.
- AMT Manufacturing has been manufacturing the predicate device (K951622) since 1990, and our professional staff has been providing ongoing advisory service to clinics that use the device.
- Minor changes have been made to the device, none of which effect performance specifications or have an adverse impact on safety or effectiveness.
- The operating principles of the AMT Therapeutic Table permit application of effective distraction tensions to the lumbar spine.
- The important basic parameters contributing to the safety & effectiveness of the device include the use of air pressure as the energy source, the ramp characteristics employed in applying distraction tensions, the release rate of tensions and relaxation cycles, the cyclic periodicity, the upper limits on distraction tensions and in addition, the positioning of the patient and the means of fixing the upper body.
- The fact that the patient can, at will, release all therapy tensions completely & immediately through releasing the handgrips, is an important safety factor.
- In addition, there is a preset high limit of therapy tension which the unit is set not to exceed. If for any reason, this high limit is exceeded, there is a complete and immediate automatic shut down of the unit.
- Each unit has a factory preset calibration number which can be verified by the operator to ensure that the factory settings have not changed; factory settings are also password protected.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2000

Mr. Bill Deacon
President
AMT Manufacturing Inc.
510 Rowntree Dairy Road, #5
Woodbridge, Ontario L4L 8H2, Canada

Re: K001401
Trade Name: AMT Therapeutic Table
Regulatory Class: II
Product Code: ITH
Dated: April 25, 2000
Received: May 3, 2000

Dear Mr. Deacon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) : K001401

Device Name : *AMT Therapeutic Table*

Indications For Use :

- The AMT Therapeutic Table is designed to relieve pressure on structures that may be causing lower back pain.
- It relieves the pain associated with herniated discs, degenerative disc disease, posterior facet syndrome and radicular pain.
- It achieves these effects through decompression of intervertebral discs, that is, unloading, due to distraction & positioning.
- This therapy provides a primary treatment modality for the management of pain & disability for patients presenting with incapacitating lower back pain.
- It has been found to provide relief in a variety of conditions involving anatomical dysfunctions of the lumber spine that generate localized low back pain as well as peripheral radiation, including patients with protruding or herniated intervertebral discs, degenerative discs, as well as those with acute facet problems.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Donna R. Lochner

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001401